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(54) Title: **A PHARMACEUTICAL AYURVEDIC PREPARATION**

(57) Abstract: The present invention relates to a process on ayurvedic preparation comprising in the steps of subjecting silver, mercury, sulphur and arsenic trisulphide to the steps of detoxification, grinding the detoxified mercury and silver in the presence of a citrus juice and then adding detoxified sulphur and again subjecting to the step of grinding to obtain a greyish black powder, adding detoxified arsenic trisulphide thereto and subjecting to the step of grinding, imparting a shape such as a ball thereto, coating the ball with detoxified sulphur in the presence of a citrus juice and subjecting the coated ball to the step of slow firing, adding detoxified arsenic trisulphide and firing, repeating said steps of addition and firing ground in a citrus juice such that the weight of the ball is reduced by at least 10 % to obtain an intermediate, adding serpentine and delphenium root thereto.



WO 01/17540

PCT/IN99/00042

TITLE OF THE INVENTION

A PHARMACEUTICAL AYURVEDIC PREPARATION

FIELD OF INVENTION

5 This invention relates to a pharmaceutical ayurvedic preparation for the treatment of leukemia. The preparation of the present invention has a particular application for the treatment of acute myeloid leukemia, acute promyelocytic leukemia and acute lymphoblastic leukemia. The present invention also relates to a process for
10 preparing the pharmaceutical ayurvedic preparation.

PRIOR ART

Chemical pharmaceutical preparations are normally prescribed for treatment of leukemia. No prior public literature is known for an ayurvedic preparation for
15 treatment of leukemia.

OBJECTS OF THE INVENTION

An object of this invention is to propose a novel ayurvedic preparation for treatment of leukemia.
Another object of this invention is to propose an ayurvedic
20 preparation for treatment of leukemia and which does not have any side effects.

DESCRIPTION OF THE INVENTION

According to this invention, there is provided a process for the preparation of an ayurvedic preparation comprising
25 in the steps of subjecting silver, mercury, sulphur and arsenic trisulphide to the steps of detoxification, grinding the detoxified mercury and silver in the presence of a citrus juice and then adding detoxified sulphur and again subjecting to the step of grinding to obtain a
30 greyish black powder, adding detoxified arsenic trisulphide thereto and subjecting to the step of grinding,

imparting a shape such as a ball thereto, coating the ball with detoxified sulphur in the presence of a citrus juice and subjecting the coated ball to the step of slow firing, adding detoxified arsenic trisulphide and firing, repeating said steps of addition and firing ground in a citrus juice such that the weight of the ball is reduced by at least 10% to obtain an intermediate, adding serpentine and delphenium root thereto.

The expression detoxification used herein is not intended to imply that silver, mercury, sulphur and arsenic trisulphide are treated such as to detoxify the elements in the mixture stage, but to imply that such elements do not exhibit any adverse side effects in the end preparations.

In accordance with this invention, silver in a purified form which is subjected to a step of detoxification. Such a step of detoxification consists in converting silver bars into sheets and then to repetitive steps of heating and introduction into sesame oil. By way of example and without implying any limitation, such a step of heating and introducing into sesame oil is repeated several times, such as seven times.

Thereafter, the treated silver is again heated and then introduced into butter milk. The step of heating and introduction into butter milk after each step of heating is also repeated several times, such as seven times.

The partially detoxified silver is again heated and then introduced into cow urine and which step is repeated several times, such as seven times.

The treated silver is again heated and introduced into a herbal composition. Such a step of heating and introduction into a herbal composition is again preferably repeated several times, such as seven times. The herbal composition comprises amla, harar and behera and present preferably in equal parts.

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The treated silver is again heated several times and then after each step of heating is treated with kutli. Such a step is also repeated several times, such as seven times. The aforesaid step consists in the detoxification of silver.
5 The process of the present invention includes the step of detoxification of mercury. For this purpose, an amalgam is first prepared from a mixture of copper, which may be in the form of wire, in lemon juice and mercury. Preferably 1/2-1/8 parts of copper wire is added to every one part of mercury which is then ground to obtain an
10 amalgam. Such an amalgam is then subjected to a step of distillation to extract mercury therefrom. The step of grinding and distillation is effected several times in order to obtain detoxified mercury. Preferably but without
15 implying any limitation to the step of detoxification is carried seven times.

The next step is the process consists in the purification of sulphur. For this purpose, crystalline sulphur is introduced into a crucible and having melted butter
20 therein. Preferably, equal amounts of melted butter and sulphur are introduced into the crucible and heated on a low fire. Trifla is then added to the mixture and whereby a scum of pure sulphur is formed and removed.

The process also comprises in introducing arsenic trisulphide disposed within a cotton cloth and introduced
25 into a vessel containing calcium oxide solution and then into another vessel of pumpkin juice or vice versa. The arsenic trisulphide is heated in calcium oxide solution and pumpkin juice for a period of 3 to 5 hours, such as
30 4 hours and, then dried.

The next step in the process consists in grinding detoxicated silver and mercury in the presence of citrus juice, such as lemon juice, and such that detoxicated silver is dissolved in mercury. Preferably, one part of
35 detoxicated silver is added to one part of mercury and

ground in the presence of lemon juice to form a powder. Thereafter, purified sulphur is added thereto and ground to greyish black powder. Preferably, one part of purified sulphur is added thereto. Upon grinding and obtaining a greyish black powder purified arsenic trisulphide is added to the greyish black powder in the presence of a citrus juice, such as lemon juice, which is then subjected to a step of grinding to obtain a paste. Such a paste is shaped into balls and then air dried. Preferably, one part of arsenic disulphide is added thereto.

The next step in the process consists in coating such balls with a paste of sulphur in lemon juice.

Such a ball is introduced into an earthenware vessel which is sealed with a strip of cotton and dipped in clay. The vessel is introduced into a bed containing dry cowdung which is then fired such that the temperature rises to a temperature of 500-600°C and then gradually reduces.

The vessel is then opened and arsenic trisulphide is added thereto in the presence of lemon juice and subjected to the step of firing. The step of adding arsenic trisulphide and firing is repeated 30-60 time to obtain a more potent intermediate product, and such that the weight is reduced by at least 10%.

Such an intermediate product is thereafter added to serpentine and delphenium root and ground in distilled rose water for approximately seven days repeated with sandalwood water for seven day and finally with latakasturi water for seven days to obtain a paste which is then shaped into balls.

Further objects and advantages of this invention will be more apparent from the ensuing example and clinical trials.

EXMAPLE

Silver, mercury, sulphur and arsenic trisulphide was

detoxified in a manner as described hereinabove. Thereafter, the ball was prepared consisting of:

detoxified silver = 250 gms

detoxified mercury = 250 gms

5 detoxified sulphur = 500 gms

detoxified arsenic

trifulphide= 250 gms

The ball had a weight of 1250 gms and then provided with a coating of detoxified sulphur ground in lemon juice and such that the coated ball had a weight of 1400 gms. Such a ball was then introduced into an earthen vessel or pot and sealed with a strip of cotton, dipped in clay. The vessel is introduced into a pit containing cow dung and fired. Such a process was repeated as shown in Table 1 to produce the intermediate product. Thereafter, the final product was prepared in a manner as described herein above.

T A B L E 1

| 20 | VESSEL | GROUND WITH | | PERIOD DAYS | WT. BEFORE FIRING gm | PERIOD OF FIRING days | WT. AFTER FIRING gm |
|----|--------|-------------|-------|----------------|-------------------------|--------------------------------|------------------------------|
| | | ARSENIC | LEMON | | | | |
| | | trisul- | Juice | | | | |
| | | phide | | | | | |
| | 1 | 0 | 0 | 0 | 1400 | 1 | 940 |
| | 1 | 25g | 450ml | 6 | 1120 | 1 | 975 |
| 25 | 1 | 25g | 400ml | 17 | 1100 | 1 | 940 |
| | 1 | 25g | 400ml | 22 | 1050 | 1 | 940 |
| | 2 | 25g | 400ml | 29 | 1110 | 1 | 930 |
| | 2 | 25g | 450ml | 36 | 1090 | 1 | 975 |
| | 2 | 25g | 400ml | 41 | 1070 | 1 | 940 |
| 30 | 2 | 25g | 400ml | 50 | 1040 | 1 | 940 |
| | 2 | 25g | 450ml | 58 | 1050 | 1 | 930 |
| | 2 | 25g | 550ml | 67 | 1080 | 1 | 940 |

| | | | | | | | |
|----|---|-----|-------|-----|------|---|------|
| | 2 | 25g | 500ml | 73 | 1070 | 1 | 950 |
| | 2 | 25g | 750ml | 80 | 1070 | 1 | 970 |
| | 2 | 25g | 750ml | 84 | 1050 | 1 | 970 |
| | 2 | 25g | 800ml | 89 | 1060 | 1 | 940 |
| 5 | 2 | 25g | 900ml | 96 | 1080 | 1 | 950 |
| | 2 | 25g | 900ml | 103 | 1100 | 1 | 1000 |
| | 2 | 25g | 900ml | 110 | 1120 | 1 | 970 |
| | 2 | 25g | 900ml | 116 | 1050 | 1 | 950 |
| | 2 | 25g | 900ml | 121 | 1020 | 1 | 950 |
| 10 | 2 | 25g | 750ml | 128 | 1050 | 1 | 990 |
| | 2 | 25g | 800ml | 135 | 1080 | 1 | 980 |
| | 2 | 25g | 750ml | 140 | 1050 | 1 | 950 |
| | 2 | 25g | 650ml | 148 | 1050 | 1 | 950 |
| | 2 | 25g | 700ml | 153 | 1020 | 1 | 950 |
| 15 | 2 | 25g | 700ml | 159 | 1080 | 1 | 980 |
| | 2 | 25g | 650ml | 173 | 980 | 1 | 920 |

The results of clinical trials on patients with the preparation of the present invention were as follows:

T A B L E 2

DETAILS OF THE PATIENTS WHO COMPLETED
90 DAYS OF TREATMENT FOR ACUTE
PROMYELOCYTIC LEUKEMIA WITH PRESENT
MEDICINE

| S.No. | Name/Age | Category | <u>Duration of Treatment</u> | | Status after |
|-------|----------|---------------------------------|------------------------------|------------|-------------------------------------|
| | | <u>Fresh/</u> <u>Relapse</u> | From | To | 90 days |
| <hr/> | | | | | |
| 1. | ARK/41 | F | 09.09.1997 | 30.01.1998 | Complete remission on 26.12.1997 |
| 2. | VR/40 | F | 04.12.1997 | 22.04.1999 | Complete remission on 14.03.1998 |
| 3. | PK/50 | F | 04.12.1997 | 20.03.1998 | Complete remission |

| | | | | | |
|-----|-------|-------|------------|------------|---|
| | | | | | or 16.03.1998 |
| 4. | VC/48 | R | 22.12.1997 | 15.04.1998 | Complete remission on 01.04.1998 |
| 5. | F/29 | R | 09.04.1998 | 07.12.1998 | Bone marrow not done, blood report normal |
| 6. | NS/15 | R | 18.04.1998 | 30.01.1999 | Complete remission on 25.07.1998 |
| 7. | PR/48 | F | 26.01.1999 | 15.05.1999 | Complete remission on 12.04.1999 |
| 5 | 8. | MS/28 | R | 19.02.1999 | 15.06.1999 Complete remission on 11.06.1999 |
| 9. | PS/29 | R | 25.03.1999 | 05.07.1999 | Complete remission on 03.07.1999 |
| 10. | MN/30 | R | 30.03.1999 | 10.07.1999 | Complete remission on 05.07.1997 |

F-Fresh, R-Relapse

T A B L E 3

10 DETAILS OF BONE MARROW OF THE PATIENTS WHO
COMPLETED 90 DAYS OF TREATMENT FOR ACUTE
PROMYELOCYTIC LEUKEMIA

| S.No. | Name/Age | Before Ayurvedic treatment | After 90 days of Ayurvedic treat- ment |
|-------|----------|---|--|
| 1. | ARK/41 | BM no.5239863, replaced with abnormal promyelocytes-M3 | PS and BM no. 523986-D, is free of evidence of M3, normal hemopoietic cell |
| 15 | 2. VR/40 | Bone marrow shows abnormal promyelocytes-M3 | Bone marrow in remission, no |

| | | | |
|-----|-------|---|--|
| | | | promyelocytic cells seen. |
| 3. | PK/50 | Bone marrow replaced with abnormal promyelocytes-M3 | Bone marrow in remission with normal cells |
| 4. | VC/48 | Bone marrow shows hyper granulated M3 cells | Bone marrow in remission with normal hemopoitic cells |
| 5. | F/29 | Bone marrow shows abnormal promyelocytes-M3 | Bone marrow not done |
| 6. | NS/15 | Bone marrow shows 60-65% abnormal promyelocytes, APL relapse, N ₈₋₁₀ , L ₃₋₅ , MRBC 25% | Bone marrow in remission, no APL cells identi- fied, PS shows P ₆₄ L ₃₃ E ₂ M ₁ |
| 7. | PR/48 | Bone marrow shows hyper granulated promyelocytes AML-M3 | Bone marrow shows normal hemopoitic with mild megalo- blastic change. There is no morphological evidence of residual leukemia |
| 8. | MS/28 | Bone marrow in relapse- AML-M3 | Bone marrow shows normal hemopoitic. No leukemic cells identified |
| 9. | PS/29 | Bone marrow shows total replacement by abnormal hyper granular promyelocytes | Bone marrow shows normal hemopoitic cells of all series. No evidence of leuk- emia seen |
| 10. | MN/30 | Bone marrow shows abnormal | Bone marrow shows |

promyelocytes along with
few normal neutrophils-
AML-M3 relapse

normal hemopoietic
cells in all
series. No
evidence of
residual leukemia

T A B L E
DETAILS OF BLOOD REPORT OF TREATED APLM CASES

| S. No. | Name/Age | Blood report | First day | After 30 days | After 60 days | After 90 days |
|--------|----------|--------------|--|--|---|---|
| 1. | ARK/41 | Hb gm% | 7.1 | 9.9 | 13.5 | 14.8 |
| | | TLC | 1100 | 1450 | 5100 | 3100 |
| | | DLC | N ₁₀ L ₃₀ Abn ₆₀ | N ₃₁ L ₆₉ | N ₆₀ L ₃₄ E ₆ | N ₅₇ L ₂₇ E ₁₀ M ₄ |
| | | ESR | 138 | 37 | 8 | - |
| | | Platelets | 19000 | 258000 | 172000 | 174000 |
| 2. | VR/40 | Hb gm % | 5.6 | 8.2 | 9.6 | 10.0 |
| | | TLC | 1600 | 620 | 3200 | 3900 |
| | | DLC | N ₃₅ L ₂₉ E ₂ M ₂ Abn ₃₀ | N ₃₂ L ₂₂ E ₄ M ₂ Abn ₂₀ | N ₄₀ L ₃₈ E ₄ Abn ₁₈ | N ₇₃ L ₂₁ E ₄ M ₂ |
| | | ESR | - | - | - | - |
| | | Platelets | 40000 | 180000 | 200000 | 200000 |
| 3. | PK/50 | Hb gm % | 10.2 | 9.3 | 10.1 | 13.9 |
| | | TLC | 2000 | 6800 | 7000 | 9000 |
| | | DLC | N ₇ L ₁₀ M ₂ Abn ₈₁ | N ₇₀ L ₃₀ | N ₆₆ L ₃₃ E ₁ | N ₆₃ L ₃₇ |
| | | ESR | - | - | 10 | - |
| | | Platelets | 35000 | 25000 | 252000 | 330000 |
| 4. | VC/48 | Hb gm % | 8.0 | 9.5 | 11.8 | 9.6 |
| | | TLC | 28000 | 650 | 7500 | 4800 |
| | | DLC | N ₃₀ L ₃₅ E ₅ M ₄ Abn ₂₆ | N ₂₀ L ₈₀ | N ₅₈ L ₂₆ M ₂ Abn ₄ | N ₇₉ L ₁₃ Abn ₄ |
| | | ESR | 75 | - | - | - |
| | | Platelets | 110000 | 22000 | 85000 | 120000 |
| 5. | F/29 | Hb gm % | 9.0 | 9.0 | 5.0 | 9.6 |

| | | | | | | |
|-----|-------|-----------|---|---|---|---|
| | | TLC | 4900 | 4900 | 2500 | 1000 |
| | | DLC | N ₈ L ₄₇ M ₅ Abr ₄₀ | N ₈ L ₄₅ M ₅ Abr ₄₀ | N ₄₅ L ₅₄ B ₁ | N ₂₆ L ₅ E ₁ Abr ₄₆ |
| | | ESR | - | - | 90 | 130 |
| | | Platelets | 75000 | 75000 | 18000 | 55000 |
| 6. | NS/15 | Hb gm % | 12.9 | 8.4 | 11.0 | 11.7 |
| | | TLC | 400 | 63200 | 7900 | 8500 |
| | | DLC | N ₆₄ L ₃₆ | N ₅ L ₁₀ Abr ₈₅ | N ₅₇ L ₄₀ E ₃ | N ₆₀ L ₃₇ E ₃ |
| | | ESR | - | 42 | 5 | 5 |
| | | Platelets | 130000 | 64000 | 238000 | 218000 |
| 7. | PR/48 | Hb gm % | 12.7 | 10.2 | 10.5 | 11.4 |
| | | TLC | 2000 | 3000 | 3500 | 5500 |
| | | DLC | N ₇ L ₄₃ Abr ₅₀ | N ₁₃ L ₂₇ E ₄ Abr ₅₆ | N ₄₈ L ₃₇ E ₆ Abr ₂ B ₁ | N ₅₅ L ₄₁ B ₁ Abr ₂ |
| | | ESR | 43 | - | - | - |
| | | Platelets | 76000 | 90000 | 298000 | 310000 |
| 8. | MS/28 | Hb gm % | 7.0 | 10.5 | 13.0 | 14.3 |
| | | TLC | 12200 | 5700 | 7200 | 9200 |
| | | DLC | N ₈ L ₃₀ Abr ₆₂ | N ₅₅ L ₄₄ E ₁ M ₂ | N ₇₃ L ₂₂ E ₅ | N ₆₄ L ₃₃ E ₃ |
| | | ESR | 48 | 5 | - | - |
| | | Platelets | 36000 | 103000 | 141000 | 169000 |
| 9. | PS/29 | Hb gm % | 8.4 | 12.2 | 15.0 | 14.9 |
| | | TLC | 2240 | 2900 | 5200 | 4600 |
| | | DLC | N ₅ L ₁₀ M ₅ Abr ₇₀ | N ₃₃ L ₄ L ₅₀ E ₂₄ 4 ^M ₁₃ 4 ^B ₀ 3 | N ₄₆ 9 ^L ₃₃ 2 ^E ₈ 3 ^M ₁₁ 2 ^B ₀ 4 | N ₄₈ 7 ^L ₃₀ 5 ^E ₈ 6 ^M ₁₂ 1 ^B ₀ |
| | | ESR | - | - | 5 | 7 |
| | | Platelets | 25000 | 298000 | 202000 | 189000 |
| 10. | MN/30 | Hb gm % | 6.5 | 9.0 | | 9.8 |
| | | TLC | 8200 | 7300 | | 5600 |
| | | DLC | N ₂₇ L ₄₈ E ₁ Abr ₂₄ | N ₇₁ L ₂₃ M ₆ | | N ₈₂ L ₁₇ M ₁ |
| | | ESR | - | - | | 60 |
| | | Platelets | 120000 | 230000 | | 150000 |

N-Neutrophils, L-Lymphocyte, E-Eosinophils, M-Monocyte, B-Basophil;
Abr-Abnormal cell

DETAILS OF LIVER, KIDNEY FUNCTION AND LIPID PROFILE OF THE PATIENTS
TREATED FOR ACUTE PROMYELOCYTIC LEUKEMIA

| S.no. | Name/Age | Pre Ayurvedic treatment | | | After 90 days of Ayurvedic treatment | | |
|-------|----------|---|---|--|---|-----------------------|--|
| | | LFT | Lipid profile | KFT | LFT | Lipid profile | KFT |
| 1. | ARK/41 | NA | NA | NA | Bilirubin (T)-1.2 mg/dl Bilirubin(D)-0.3 mg/dl Protein total -7.8 mg/dl SGOT-29, SGPT-35 Alk.P.-161 | NA | Blood -23 mgs/dl Serum-0.8 mg/dl creat-inine |
| 2. | VR/40 | NA | NA | NA | NA | NA | NA |
| 3. | PK/50 | Bilirubin(T)-0.4 mgs/100ml Bilirubin(C)-0.2 mgs/100ml SGOT-75u/l, SGPT-35 Alk.P.-324 u/l | NA | Blood urea NA -21mgs/100 Serum creatinine -1.1 mgs/100ml | NA | NA | Blood -34mgs % serum creat-inine-1.3mgs % |
| 4. | VC/48 | Bilirubin(T)-0.7 mgs Bilirubin(C)-0.3 mgs Protein total-7.0 gm% Albumin-3.9gm% Globulin-3.1gm% SGOT-20u/l, SGPT-25 Alk.P.-138 | Total cholesterol-168 mg/dl HDL cholesterol-380 mg/dl VLDL cholesterol-29 mg/dl LDL cholesterol-101 mg/dl Triglycerides-433 mg/dl | Blood urea -26 mg% Serum creatinine -1.0 mg% Serum uric acid-4.9 mg% | Bilirubin(T)-0.72 mg/dl Bilirubin(D)-0.3 mg/dl Protein total -6.2 mg/dl Albumin-3.6 SGOT-20u/l, SGPT-25 Alk.P.-430 | Cholesterol-198 mg/dl | NA |

| | | | | | | | |
|----|-------|---|--|--|---|---|--|
| 5. | F/29 | NA | NA | NA | NA | NA | NA |
| 6. | NS/15 | Bilirubin(T)-0.5 mg/dl Bilirubin(D)-0.3 mg/dl Protein total- 7.1 g/dl Albumin-3.4 g/dl SGOT-10u/l, SGPT-12 Alk.P.-103 | Total cholesterol- 185 mg% HDL cholesterol- 42 mg% VLDL cholesterol- 21 mg% LDL cholesterol- 122 mg% Triglycerides- 105 mg% | Blood sugar -90 mg% Blood urea -19 mg% Serum creatinine -0.8 mg% | NA | NA | NA |
| 7. | PR/48 | Bilirubin(T)-1.57 mg/dl Bilirubin(D)-0.14 mg/dl Bilirubin(ID)-1.43 mg/dl Protein total-6.9 mg/dl SGOT-29, SGPT-22 Alk.P.-183.8 | NA | Blood-34 mgs/dl urea Serum-1.2mg/dl creatinine Uric-2.8mg/dl acid | Bilirubin(T)- 0.6mg% Bilirubin(D)- 0.6 mg% Bilirubin(ID)- 0.5 mg% Protein total- 6.4 mg% Albumin-3.7 mg% SGOT-49u/l, SGPT-38u/l, GGPT-17u/l Alk.P.-17 u/l | Total choles- trol-198 mg/dl HDL cholesterol -49 mg% LDL cholesterol -150 mg% VLDL cholest- rol-27 mg% Triglycerides -136 mg% Calcium-9.7 mg% Phosphorus- 4.3 mg% Sodium-114 meq/l Chloride- 107 meq/l | Blood urea -33 mg/dl Serum creatinine -0.5 mg/dl |
| 8. | MS/28 | NA | NA | NA | NA | NA | NA |
| | | | | | Bilirubin(T) -0.5 mg/dl Protein total -6.6 g/dl Albumin-4.2 g/dl SGOT-62 u/l, SGPT-138 u/l Alk.P.-8 u/l | Total chol- estrol-146 mg/dl HDL choles- trol-32 mg/ dl LDL choles- trol-53 mg/ dl Triglycer- ides-306 mg/dl | Blood urea -33 mg/dl Serum creatinine -0.5 mg/dl |

| | | | |
|-----|-------|--|----|
| 9. | PS/29 | <p> Bilirubin(T)- 0.4 mg/dl Bilirubin(D)- -0.2 mg/dl Bilirubin(ID)- 0.2 mg/dl Protein total- 7.6 g/dl Albumin-4.4 g/dl SGOT-126 u/l, SGPT-49 u/l GGTP-38 u/l Alk.P.-217 u/l </p> <p> Total cholest- rol-205 mg/dl HDL cholestrol- 31.25 mg/dl VLDL cholestrol- 26.99% LDL cholestrol- 118.42 mg/dl Triglycerides- 433 mg/dl </p> <p> Blood urea -45 mg/dl Serum creat- inine-0.90 mg/dl Calcium- 10.1 mg/dl Phosphorus- 4.1 mg/dl Sodium-147 mEq/l Chloride- 103 mEq/l Potassium- 4.20 mEq/l </p> <p> Bilirubin(T)- -0.7 mg/dl Bilirubin(D)- 0.2 mg/dl Bilirubin(ID)- 0.5 mg/dl Protein total- 7.7 g/dl Albumin-4.6 g/dl SGOT-253 u/l, SGPT-365 u/l GGTP-89 u/l Alk.P.-473 u/l </p> <p> Total cholest- rol-156 mg/dl HDL cholest- rol-22.15 mg% LDL cholest- rol-94.09 mg% VLDL cholest- rol-27.35 mg% Trigly- cerides-4.90 mEq/l 187 mg/dl </p> <p> Blood urea- 17 mg/dl Serum creati- nine-1.0 mg/d Calcium-9.7 mg/dl Phosphorus- 2.9 mg/dl Sodium-150 mE mEq/l Chloride-105 mEq/l Potassium- 4.90 mEq/l </p> | 13 |
| 10. | MM/30 | <p> Bilirubin(T)- 1.7 mg/dl Bilirubin(D)- 1.13 mg/dl Bilirubin(ID)- 0.57 mg/dl SGOT-28 u/l, SGPT-35 u/l, Alk.P.-229 u/l </p> <p> Total cholest- rol-185 mg/dl HDL cholest- rol-26mg/dl VLDL cholest- rol-93 mg/dl LDL cholest- rol 106 mg/dl Triglycerides- 506 mg/dl </p> <p> Blood urea 46 mg/dl Serum creat- inine-1.05 mg/dl Calcium- 8.25 mg/dl </p> <p> Bilirubin(T)- 0.7 mg/dl Bilirubin(D)- 0.3 mg/dl SGOT-22.8iu/l SGPT-27.6iu/l Alk.P.-360.5 iu/l </p> <p> Total cholestrol-mg/dl 136.8 mg/dl HDL cholest- rol-46.2 mg/dl LDL cholest- rol-56.5 mg/dl VLDL cholest- rol-34.1 mg/dl </p> <p> Serum urea-29.3 mg/dl Serum creatinine -1.0 mg/dl Serum creatinine -46.2 mg/dl </p> | |

I CLAIM:

1. A process or ayurvedic preparation comprising in the steps of subjecting silver, mercury, sulphur and arsenic trisulphide to the steps of detoxification, grinding the
5 detoxified mercury and silver in the presence of a citrus juice and then adding detoxified sulphur and again
subjecting to the step of grinding to obtain a greyish black powder, adding detoxified arsenic trisulphide thereto
and subjecting to the step of grinding, imparting a shape
10 such as a ball thereto, coating the ball with detoxified sulphur in the presence of a citrus juice and subjecting
the coated ball to the step of slow firing, adding
detoxified arsenic trisulphide and firing, repeating
said steps of addition and firing ground in a citrus juice
15 such that the weight of the ball is reduced by at least
10% to obtain an intermediate, adding serpentine and
delphenium root thereto.

2. A process as claimed in claim 1 wherein the coated
balls are introduced into an earthen vessel, sealed and
20 then fired in the presence of cow dung.

3. A process as claimed in claim 1 wherein silver is
detoxified by heating silver sheets to a red hot state,
and then introducing into sesame oil, subjecting the sheets
to repeated steps of heating and treatment with sesame
25 oil.

4. A process as claimed in claim 3 wherein the sesame
treated silver is subjected to repetitive steps of heating
and then treating with butter milk.

5. A process as claimed in claim 4 wherein the butter
milk treated silver is subjected to repetitive steps of
30 heating and then treating with cow urine.

6. A process as claimed in claim 5 wherein the cow urine
treated silver is then subjected to repetitive steps of
heating and treatment in a herbal composition comprising
35 amla, harar and bahera.

7. A process as claimed in claim 1 wherein the herbal treated silver is subjected to repetitive steps of heating and treatment with kulthi.

5 8. A process as claimed in claim 1 wherein the citrus juice is lemon juice.

9. A process as claimed in claims 3 to 7 wherein said repetitive steps comprise 7 repetitive steps.

10 10. A process as claimed in claim 1 wherein the step of detoxification of mercury comprises in preparing an amalgam of copper, mercury and a citrus juice, subjecting such an amalgam to repeated steps of distillation to obtain detoxified mercury.

15 11. A process as claimed in claim 1 wherein the step of detoxification of sulphur comprises in heating crystalline sulphur in the presence of melted butter, and then introducing into triffla to obtain a scum of pure sulphur which is then removed therefrom.

20 12. A process as claimed in claim 1 wherein the step of detoxification of arsenic trisulphide comprises in wrapping arsenic trisulphide in cotton cloth and then introduced in a vessel of calcium oxide solution and into another vessel of pumpkin juice and boiled each time for a period of 3 to 5 hours.

25 13. A process as claimed in claim 1 wherein one part of detoxified silver is ground with one part of detoxified mercury in a citrus juice and that one part of detoxified sulphur is then added thereto obtain a greyish black powder.

30 14. A process as claimed in claim 12 wherein one part of arsenic trisulphide ground in a citrus juice is added to the greyish black powder and made into a shape.

35 15. A process as claimed in claim 14 wherein one part of detoxified sulphur is ground in citrus juice and coated to said shape and then introduced in said vessel and tired in cowdung.

16. A process as claimed in claim 1 wherein vessel containing said fired mixture is opened and further arsenic trisulphide ground in the presence of lemon juice is added, the vessel closed and again fired and subjected to repeated steps to obtain a potent preparation.

17. A process as claimed in claim 16 wherein one part of the potent preparation is added to one part of serpentine and one part of delphenium root and ground in distilled rose water followed sandal wood water and to latakasturi water.

18. A process for producing an ayurvedic preparation for the treatment of leukemia substantially as herein described.

PATENT COOPERATION TREATY

PCT

2

REC'D 27 SEP 2001

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| | | |
|--|---|---|
| Applicant's or agent's file reference IN/PA-210 | <div style="display: flex; justify-content: space-between;"> <div> FOR FURTHER ACTION </div> <div> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) </div> </div> | |
| International application No. PCT/IN99/00042 | International filing date (day/month/year) 07/09/1999 | Priority date (day/month/year) 07/09/1999 |
| International Patent Classification (IPC) or national classification and IPC A61K35/78 | | |
| Applicant PRAKASH, Vaidya, Balendu | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

- | | | |
|------|-------------------------------------|---|
| I | <input checked="" type="checkbox"/> | Basis of the report |
| II | <input type="checkbox"/> | Priority |
| III | <input type="checkbox"/> | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV | <input type="checkbox"/> | Lack of unity of invention |
| V | <input checked="" type="checkbox"/> | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI | <input type="checkbox"/> | Certain documents cited |
| VII | <input type="checkbox"/> | Certain defects in the international application |
| VIII | <input checked="" type="checkbox"/> | Certain observations on the international application |

| | |
|---|--|
| Date of submission of the demand 29/03/2001 | Date of completion of this report 25.09.2001 |
| Name and mailing address of the international preliminary examining authority: <div style="display: flex; align-items: center;"> <div> European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 </div> </div> | Authorized officer Ludwig, G Telephone No. +49 89 2399 8698 |



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IN99/00042

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-13 as originally filed

Claims, No.:

2-14,16,17 as originally filed

1,15,18 as received on 11/09/2001 with letter of 24/08/2001

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IN99/00042

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|------|--------|------|
| Novelty (N) | Yes: | Claims | 1-18 |
| | No: | Claims | |
| Inventive step (IS) | Yes: | Claims | 1-18 |
| | No: | Claims | |
| Industrial applicability (IA) | Yes: | Claims | 1-18 |
| | No: | Claims | |

2. Citations and explanations
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IN99/00042

Item V:

1. There appears to be no relevant prior art.

The process of preparing/use of an ayurvedic preparation as described in claims 1-18 appears therefore to be novel and inventive.

According to the data presented in the application said preparation can be used successfully for the treatment of leukemia.

Item VIII:

2. In claim 1 (line 2) the word "in" should be deleted for the sake of clarity.
3. The word "fried" in claim 15 does not appear to be originally disclosed.

Only the word "fired" appears to be disclosed originally (cf. claim 2).

24/08/2001 19:00 91-33-2406

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Dr (Mrs) S. Banerjee

From

European Patent Office (IPEA),

To

G Ludwig Esq.

Attn.

Examiner

No. of Pages

(including this page)

From

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INDIA

24.8.2001

Date

4989 2399-4465

Facsimile No.

ONE + ONE

Dear Sir,

Re: Patent Application No. PCT/IN99/00042 of 7.9.99
 of Prakash Vaidya Balendu

Kindly refer to the international preliminary examination report dated 27.7.2001 issued in respect of the instant patent application of which we are to submit as follows:

Regarding the objections, we suggest to amend claims 1, 15 and 18 to read as follows:

Claim 1: "A process for preparing an ayurvedic preparation comprising in the steps of subjecting silver, mercury, sulphur and arsenic trisulphide to the steps of detoxification, grinding the detoxified mercury and silver in the presence of a citrus juice and then adding detoxified sulphur and again subjecting to the step of grinding to obtain a greyish black powder, adding detoxified arsenic trisulphide thereto and subjecting to the step of grinding, imparting a shape such as a ball thereto, coating the ball with detoxified sulphur in the presence of a citrus juice and subjecting the coated ball to the step of slow firing, adding detoxified arsenic trisulphide and firing, repeating said steps of addition and firing ground in a citrus juice such that the weight of the ball is reduced by at least 10% to obtain an intermediate, adding serpentine and delphinium root thereto".

Contd...p2/-

24-08-2001

Empfangszeit 24. Aug. 15:29

Printed: 14-09-2001

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24/08/2001 19:00 91-37-2406292

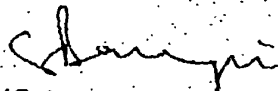
L S DAVAR & CO

Claim 15: "A process as claimed in claim 14 wherein one part of detoxified sulphur is ground in citrus juice and coated to said shape and then introduced in said vessel and fried in cowdung".

Claim 18: "A process for preparing an ayurvedic preparation for the treatment of leukemia as claimed in claims 1 to 17".

Please let us know if the above mentioned amendments meets your requirements.

Yours sincerely,



(S Banerjee)

SB/am

Empfangszeit 24. Aug. 15:29

24-08-2001

